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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,486	02/05/2002	Henri Vial	1721-45	6634

7590 05/25/2004

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EXAMINER

KUMAR, SHAILENDRA

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 05/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,486

Applicant(s)

VIAL ET AL.

Examiner

SHAIENDRA - KUMAR

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 18-28 is/are rejected.
- 7) ☒ Claim(s) 14-17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

The Notice of Allowance mailed 3/4/2004, is hereby withdrawn, and following office action is in order.

Claims 1-28 are pending in this application.

It is noted that the priority claim inserted in the preliminary amendment "A" is incorrect, as it refers to wrong PCT and wrong date. A correction is requested.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-13, 18-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are directed to precursors of drug with ant malarial action , characterized in that it concerns quaternary bis-ammonium salts and that they correspond to general formula (I).

The formula (I) is a tertiary amine and not quaternary amine as claimed herein, thus rendering claims confusing and indefinite.

Claim 19 is indefinite because the definition of Z is C1-C8 alkyl. When Z is alkyl, the valence of carbon is not satisfied, thus rendering claim indefinite. Also, this claim has a period after the definition of R1 and R2, thus consisting of two sentences, rendering the claim confusing and indefinite.

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3. Claims 23 and 25 recites the limitation "precursor" in line 1. There is insufficient antecedent basis for this limitation in the claim. These claims depend on claim 20, which is a method claim, thus lacking antecedent basis.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for anti malarial action, and antibabesiasis, does not reasonably provide enablement for vast number of infectious diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)).

These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of the working examples, predictability of the prior art, state of the prior art and the amount of the experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below:

Nature of the invention: The claim is drawn to a method of treating infectious disease in an animal in need of said treatment by administering compound of formula (I).

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Breadth of the claim: The complex nature of the claim greatly exacerbated by breadth of the claim. The claim encompasses treating any infectious disease broadly in a mammal including a human.

Guidance of the specification: The guidance given by the specification as to how one would administer the claimed compounds to a subject in order to treat malaria and babesiasis only.

Working examples: The working examples provided by the specification are directed to the ant malarial and antibabesiasis activity only.

State of the art:: While the state of the art is relatively high with regard to the treatment of specific infectious diseases, the state of the art with regard to single agent for treating any infectious disease is unknown. In particular, there is no known single antiinfectious agent which is effective against all the infectious diseases.

Predictability of the art:: The lack of significant guidance from the specification or prior art with regard to the actual treatment of all infectious diseases in a mammal including humans subject with the claimed compounds makes practicing the claimed invention unpredictable.

The quantity of experimentation necessary: Applicants fail to provide guidance and information as to allow the skilled artisan to ascertain which particular type of infectious disease against the claimed antiinfectious agent is effective without undue experimentation. The limited disclosure of the antiparasitic, and especially, anti malarial, is noted but does not support various infectious diseases.

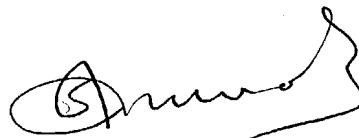
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6. Claims 14-17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAILENDRA - KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571)272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SHAILENDRA - KUMAR
Primary Examiner
Art Unit 1621

S.Kumar
5/24/04